[10123/03501]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Delaney et al.
Serial No.	:	10/668,629
Filed	:	September 23, 2003
For	:	Mid-stream Flushing Adapter
Group Art Unit	:	3728
Examiner	:	Jerrold D. Johnson

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By: Oleg F. Kaplun, Reg. No. 45,559 Date: November 21, 2005

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TRANSMITTAL

In response to the Final Office Action dated July 19, 2005 and the Advisory Action dated September 30, 2005, transmitted herewith please find a Notice of Appeal for filing in the above-identified application. Applicants hereby request a one-month extension. Please charge the Credit Card of **Fay Kaplun & Marcin, LLP** in the amount of $620.00 (PTO-Form 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

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Respectfully submitted,

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PATENT
Attorney Docket No.: 10123 - 03501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Delaney et al.	)	
	)	
Serial No.: 10/668,629	)	Group Art Unit: 3728
	)	
Filed: September 23, 2003	)	Examiner: Jerrold D. Johnson
	)	
For: MID-STREAM FLUSHING ADAPTER	)	**Board of Patent Appeals and Interferences**
	)	

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed [Notice of Appeal Date], and pursuant to 37 C.F.R. § 41.37, Appellants present their appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 20 in the final Office Action dated July 19, 2005. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Boston Scientific Scimed, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1 - 20 stand rejected in the Final Office Action. The final rejection of claims 1 - 20 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention describes, in one aspect, a protective package 10 for an elongated medical device 14. *Specification*, p. 7, lines 26 - 29, Fig. 1. The package 10 comprises a protective sheath and a hydration opening 19. *Id.* at p. 8, lines 13 -15, Fig. 1. The protective sheath includes a lumen sized to receive a body of the elongated medical device. A first end 30 of the sheath is adapted to receive a distal end of the elongated medical device and a second end 32 of the sheath is adapted to receive a proximal end of the elongated medical device. *Id.* at p. 8, lines 5 - 8, Fig. 1. The hydration opening 19 is disposed between the first and second ends of the sheath. *Id.* at p. 8, lines 21 -23, Fig. 1.

In another aspect, the present invention describes a catheter kit comprising a catheter, a tubular enclosure 12 having first and second ends 30,32 and a hydration opening 19.

Id. at p. 8, lines 5 - 8, Fig. 1. The catheter has a shaped distal tip 36. *Id.* at p. 9, lines 23 - 26. The tubular enclosure 12 has a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter. *Id.* at p. 8, lines 2 - 4. The first end 30 of the tubular enclosure 12 is adapted to receive the shaped distal tip 36. The second end 32 of the tubular enclosure 12 is adapted to receive a proximal end of the catheter. The hydration opening 19 extends into an interior of the tubular enclosure 12 between the first and second ends 30,32 thereof. The hydration opening 19 is positioned so that a desired proportion of flow thereinto is directed toward the first and second ends 30,32. *Id.* at p. 8, lines 21-25.

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1 - 9, 12, 13 and 15 -17 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,569,106 to Ullman et al. ("Ullman").

II. Whether claims 1 - 7 and 9 - 14 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,588,588 to Samuels.

III. Whether claims 8 and 15 - 20 are unpatentable under 35 U.S.C. § 103(a) as obvious over Samuels in view of Ullman.

IV. Whether claims 1, 3, 6 - 9, 12, 13, 15, 16 and 19 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,861,395 to Taniguchi.

V. Whether claim 4 is unpatentable under 35 U.S.C. § 103(a) as obvious over

Taniguchi in view of U.S. Patent No. 4,805,611 to Hodgkins.

VI. Whether claims 1, 4, 7, 9, 10 and 11 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,597,264 to Laak.

7. Argument

I. The Rejection of Claims 1 - 9, 12, 13 and 15 -17 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 6,569,106 to Ullman et al. Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1 - 9, 12, 13 and 15 -17 were rejected under 35 U.S.C. 102(b) as being anticipated by Ullman. *7/19/05 Office Action*, p. 2. Ullman discloses a medical guide wire containment device consisting of a housing which receives and retains one or more guide wires. *Ullman*, Abstract. A leading tip of the guide wire is inserted into an isolation chamber in the housing via a funnel. *Id.* at col. 4, lines 49 - 52. The leading tip follows a fixed spiraling guide preventing entanglement of the guide wire while being inserted into the isolation chamber. *Id.* at col. 5, lines 13 - 16. A lagging tip of the guide wire remains exposed so that a user may pull the guide wire from the housing for reuse. *Id.* at col. 5, lines 34 - 37.

B. Ullman Does Not Disclose a Protective Sheath Including a Lumen Sized to Receive a Body of an Elongated Medical Device, Wherein a First End of the Sheath is Adapted to Receive a Distal End of the Elongated Medical Device and a Second End of the Sheath is Adapted to Receive a Proximal End of Elongated Medical Device as Recited in Claim 1.

Claim 1 recites a protective package for an elongated medical device comprising "a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein *a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of elongated medical device*" and "a hydration opening disposed between the first and second ends of the sheath."

In the final rejection, the Examiner states that Fig. 4 of Ullman shows a protective package for an elongated medical device including a protective sheath (i.e., the fixed spiraling guide 27) and a hydration opening, as recited in claim 1. *7/19/05 Office Action*, p. 2. Appellants respectfully submit that neither the isolation chamber 13 nor the fixed spiraling guide 27 of Ullman is a protective sheath "wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device," as recited in claim 1.

Initially it is noted that, although the Examiner stated that Ullman "discloses a structure which meets the definition [of sheath], particularly with respect to the function of a sheath of a blade," *7/19/05 Office Action*, p. 5, no comparison was made between the parts of the Ullman device and that of a sheath. Specifically, it is respectfully submitted that the term sheath does not encompass all structures which receive an item. That is, a parking garage is not a sheath

for a car. Rather a sheath is a "case for a blade...or other instrument *to which it fits closely*." (Webster's Third International Dictionary, 1986).

The Examiner states that the fixed spiraling guide 27 is a sheath as claimed. Ullman states only that the guide 27 "establishes a fixed pathway to ensure the guide wire 16 will spiral in a selected manner without entanglement." *Ullman*, col. 5, lines 14-16. Fig. 4 shows this guide 27 as a coiled wall which will engage only a leading tip and a radially outer side of a wire 16 inserted into the device 10. That this guide 27 is not a sheath is made clear from Fig. 4 which shows that a width of a proximal portion of the passage through which the wire 16 will be inserted is significantly smaller than a width of the passage defined by the guide 27 -- several times smaller. Thus, it is respectfully submitted that it is improper to infer that the space within the guide 27 closely fits the wire 16. In addition to the increased width of this space within the guide 27, it is noted that Ullman provides absolutely no disclosure of the size or shape of this space in a direction perpendicular to the plane of Fig. 4 (i.e., a width of the chamber 13). Furthermore, the guide 27 ends at an open central chamber which leaves the distal portion of the wire 16 completely uncontained. Thus, Appellants respectfully submit that the spiraling guide 27 is not a sheath as recited in claim 1.

Furthermore, the Examiner maintains that the isolation chamber 13 is suitable to receive an entire guide wire 16 encompassing both its distal and proximal ends. However, it is noted that this suggestion is contrary to the disclosure of Ullman. In fact, Ullman states that "the wire is pushed all the way in [the chamber] until a small amount, such as about 1-2 cm, remains

external to the membrane." *Ullman*, col. 2, lines 60-62. A lagging tip 16a is never received by the chamber 13 so that the wire may be easily removed from the chamber 13. The Examiner states that "the funnel portion [18-20] is suitable to receive the end of the guide wire or catheter entirely within the funnel portion, and yet still allow easy removal of the guide wire or catheter from the package." *7/19/05 Office Action*, p. 6. The Examiner does not explain how the guide wire would be removed from the isolation chamber 13 if the tip 16a were not external to the chamber 13. It remains unclear how a user would pull the guide wire 16 from the chamber 13 when the tip 16a is located within the chamber 13. However, if the Examiner is implying that, while within the funnel portion, the lagging tip of the guide wire 16 could still be grasped for removal therefrom, this indicates clearly that this funnel portion also does not constitute a sheath. That is, it clearly does not fit the item inserted therein closely. As in the case of a sheath for a blade, such increased width allowing access is the very thing a sheath is designed to prevent. Thus, it is respectfully submitted that neither the chamber 13, the funnel portion thereof or the guide 27 (or any combination of these elements) constitutes a sheath as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 1 and claims 2, 4, 7, 9 and 12 - 13 which depend directly or indirectly therefrom.

C. Ullman Does Not Disclose a Protective Assembly Disposed at the First End of the Sheath, the Protective Assembly being Adapted to Maintain a Desired Shape of the Distal End as Recited in Claim 3.

Claim 3, which depends directly from claim 1, recites "a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end." In the final rejection, the Examiner states that the funnel 18 disclosed in Ullman is disposed at a first end of the sheath and maintains a desired shape of the distal end of the elongate medical device, i.e., the guide wire 16. *7/19/05 Office Action*, pp. 2-3. Appellants respectfully submit that neither the funnel 18 nor any other structure of the device 10 in Ullman may be considered "a protective assembly" as recited in claim 3.

Ullman specifically states that the funnel 18 "acts as a transition structure to enable a healthcare provider to easily insert the guide wire 16 into an entry port, such as the entry ports 21-23, of the isolation chambers 13-15." *Ullman*, col. 4, lines 52-55. The funnel 18 simply guides the guide wire 16 into the isolation chamber 13. Also, as stated above, the tip 16a remains exposed from the funnel 18. While this allows the provider to grasp the tip 16 to pull the guide wire 16 from the isolation chamber 13, the funnel 18 is no way protects the tip 16a, or any portion, of the guide wire 16.

Furthermore, a shape of the funnel 18, which is shown in Fig. 4 of Ullman, does maintain a desired shape of the distal end of the elongate medical device. Initially, Ullman never discloses that the distal end, or any end of the guide wire 16, has a preformed shape which is integral to its function or requires maintenance. In any case, the structure of the funnel 18 is

completely unsuitable for maintaining the shape of an end of the guide wire 16. The leading end may contact the funnel 18 and be directed into the isolation chamber 13 when the guide wire 16 is inserted therein, and the lagging tip (tip 16a) is exposed with the funnel 18 surrounding it, as shown in Fig. 2. The funnel 18 never encloses or encases an end of the guide wire 18 protecting the shape thereof. Thus, it is respectfully submitted that Ullman neither discloses nor suggests a " protective assembly being adapted to maintain a desired shape of the distal end," as recited in claim 3.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 3.

D. Ullman Does Not Disclose a Protective Assembly Adapted to Prevent Damage to a Curvature of the Distal End of the Elongated Medical Device as Recited in Claim 6.

Claim 6, which depends from claim 3, recites that "the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device." In the final rejection, the Examiner states that a size of the opening of the funnel 18 would accommodate the distal end of the guide wire 16. *7/19/05 Office Action*, p. 3.

Even assuming that the Examiner's statement regarding the opening of the funnel 18 were true, Appellants respectfully submit that the funnel 18 does not prevent damage to a curvature of the distal end, or any portion, of the elongated medical device. As noted above, the funnel 18 is meant to facilitate insertion of the guide wire 16 into the isolation chamber 13 by

directing the leading tip of the guide wire 16 toward a chamber port 21 at a center of the funnel 18. *Ullman*, col. 4, lines 49 - 55, Fig. 2. However, the funnel 18 does not prevent damage to a curvature of the guide wire 16, if it even possesses a curvature to begin with. For example, as understood by those of skill in the art, if the guide wire 16 is advanced toward the funnel 18 and engages the funnel 18 at angle (e.g., substantially perpendicular to a surface of the funnel 18) and/or with enough force, the funnel 18 may cause the guide wire 16 to bend, damaging the curvature thereof. Additionally, the curvature of the lagging end of the guide wire 16 is not protected by the funnel 18. That is, the tip 16a is exposed in the opening of the funnel 18. Thus, any curvature of the tip 16a is not protected by the funnel 18. It is respectfully submitted that Ullman neither discloses nor suggests that "the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device," as recited in claim 6.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 6.

E. Ullman Does Not Disclose a Sheath Adapted to Contain a Catheter with a Shape Distal Tip as Recited in Claim 8.

Claim 8, which depends from claim 6, recites "the sheath is adapted to contain a catheter with a shaped distal tip." In the final rejection, the Examiner states that the opening of the funnel 18 may or may not be needed to accommodate a shaped distal tip, because the shaped distal tip of some catheters is of a size that approximates the size of the remainder of the catheter. *7/19/05 Office Action*, p. 3. Though not cited as a reference in the rejection of claim 8, the

Examiner cites U.S. Patent No. 3,606,001 to Talonn as extrinsic evidence that one of ordinary skill in the art would modify the funnel 18 of Ullman to contain a catheter with a shaped distal tip. *Id.* Talonn shows a cardiac catheter package consisting of an elongated tubular housing portion 17 sealed at a distal end and having a removable cap 18 on a proximal end which seals a catheter in the housing portion 17. *Talonn*, col. 2, lines 33 - 44, Figs. 1, 2.

Appellants respectfully submit that Ullman does not disclose a sheath adapted to contain a catheter with a shaped distal tip. Initially, Ullman never discloses or suggests that the guide wire 16 may have a shaped distal tip. Also, the funnel 18 of Ullman is not adapted to contain a catheter with a shaped distal tip. That is, the funnel 18 does not, in fact, even contain the guide wire 16, because the tip 16a is exposed in the opening thereof. Furthermore, Ullman does not disclose that either the funnel 18 or the opening thereof is shaped to complement the guide wire 16. Appellants also respectfully submit that it remains unclear how one of ordinary skill in the art would apply the teaching of Talonn to the funnel 18 of Ullman. That is, Talonn does not include any funnel-shaped portion. In fact, the cap 18, which is sized to complement the housing portion 17, completely covers the catheter, which is contrary to the teaching of the tip 16a remaining exposed in Ullman. Ullman specifically states that the tip 16a remaining exposed serves a predefined purpose, i.e., allows the provider to grasp the guide wire 16 and pull it from the isolation chamber 13. Thus, Ullman neither discloses nor suggests that "the sheath is adapted to contain a catheter with a shaped distal tip," as recited in claim 8.

Thus, Appellants respectfully request that the Board overturn the Examiner's

rejection under 35 U.S.C. § 102(b) of claim 8.

F. Ullman Does Not Disclose the Subject Matter Recited in Claim 15.

Claim 15 recites a catheter kit comprising "a catheter having a shaped distal tip" in combination with a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter" and "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the tubular enclosure being adapted to receive a proximal end of the catheter" in combination with "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends."

The Examiner states that the fixed spiraling guide 27 of Ullman is a tubular enclosure as claimed. As noted above, Ullman provides absolutely no disclosure of the size or shape of the space within the guide 27. That is, there is no suggestion that the space might be a tube or that a diameter/width of the space corresponds to an outer diameter of the guide wire 16. Thus, applicants respectfully submit that the spiraling guide 27 is not a tubular enclosure as recited in claim 15.

Additionally, Ullman does not disclose or suggest "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the tubular enclosure being adapted to received a proximal end of the catheter," as recited in claim 15. The

tip 16a of the guide wire 16 remains external to the chamber 13, and, as such, is never received therein.

Further, Ullman does not disclose or suggest a "hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15. In support of the rejection of claim 15, the Examiner reads features of Ullman from the drawings, such as "both ends are below the port 30" and "even if the first end 26 were higher than the port 30, which it is not." Initially, it respectfully submitted that Ullman does not disclose or suggest these features recited by the Examiner. Further, patent drawings are not to scale and any inferences made by the Examiner regarding dimensions and/or structural features of the device without supporting disclosure are improper. Appellants also respectfully submit that fluid delivered to the isolation chamber 13 via the filling port 30 is never directed toward the entry port 21. Ullman states that the fluid fills the isolation chamber 13, but never discloses or suggests that any fluid would be directed toward the entry port 21. Thus, it is respectfully submitted that Ullman neither discloses nor suggests the limitations of claim 15.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 15 and claim 17 which depends therefrom.

G. Ullman Does Not Disclose a Protective Structure Disposed at the First End, the Protective Structure Maintaining a Desired Curvature of the Shaped Distal Tip as Recited in Claim 16.

Claim 16, which depends from claim 15, recites "a protective structure disposed at

the first end, the protective structure maintaining a desired curvature of the shaped distal tip." In the final rejection, the Examiner states that the funnel 18 and the port 21 are disposed at the first end and maintain the desired curvature of the shaped distal tip of the guide wire 16. Initially, it is noted that Ullman never discloses or suggests that the guide wire 16 includes a shaped distal tip, or that the shaped distal tip is curved. Also, as stated above, neither the funnel 18 nor the port 21 are suitable for maintaining curvature of a shaped distal tip, i.e., the tip 16a. That is, the funnel 18 does not engage the tip 16a, leaving it susceptible to bending and other damage. Therefore, it is respectfully submitted that Ullman does not disclose or suggest "a protective structure disposed at the first end, the protective structure maintaining a desired curvature of the shaped distal tip," as recited in claim 16.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 16.

II. The Rejection of Claims 1 - 7 and 9 - 14 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 6,588,588 to Samuels Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1 - 7 and 9 - 14 were rejected under 35 U.S.C. 102(b) as being anticipated by Samuels. *7/19/05 Office Action*, p. 7. Samuels discloses an adapter that converts medical guidewire packaging into a reusable storage device. *Samuels*, Abstract.

B. Samuels Does Not Disclose a Hydration Opening Disposed Between the First and Second Ends of the Sheath as Recited in Claim 1.

Claim 1 has been recited above. In the final rejection, the Examiner states that Samuels discloses a hydration opening, i.e., the adapter 10, disposed between the first and second ends. *7/19/05 Office Action*, p. 7.

Appellants respectfully submit that Samuels neither discloses nor suggests "a hydration opening disposed between the first and second ends of the sheath." Samuels describes a hoop packaging tube 40 consisting of a leading opening 44 and a trailing opening 48. *Samuels*, Fig. 1. An adapter 10 connecting the openings 44 and 48 includes a funnel 24 for receiving one or more guidewires 60. The guidewire 60 is inserted into the tube 40 via the adapter 10, winding wind around the tube 40 until the guidewire 60 has been fully inserted therein. *Id.* at Fig. 3. At no point does Samuels teach or suggest that the adapter 10 is suitable for receiving fluid or that fluid inserted thereinto would hydrate the tube 40. In fact, Samuels states that "[a]fter the guidewire is reinserted into the packaging tube, the adapter 10 may be removed...and the bridge connector may be reinserted to close the loop of the packaging tube." *Samuels*, col. 3, lines 40-44.

The Examiner states that a port 30 on the adapter 10 is usable as a hydration opening, and that further evidence of this use is provided in U.S. Patent No. 6,375,006 to Samuels ("'006 patent"). The '006 patent describes a flexible pipe 12 having a sealed end 14 and an open end 16 with a nozzle 20 attached thereto. It is never disclosed or suggest that the nozzle 20 is "disposed between the first and second ends" of the pipe 12. In fact, this would be contrary

to the disclosure of the '006 patent which repeatedly describes the apparatus as having one open end and one sealed end, which teaches away from the present invention. Further, the combination of these references would be improper, because Samuels teaches two open ends, whereas the '006 patent teaches only one open end. Thus, it is respectfully submitted that neither Samuels nor the '006 patent discloses or suggests "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 1 and claims 2, 4, 5, 7 and 9 - 14 which depend therefrom.

C. Samuels Does Not Disclose a Protective Assembly Disposed at the First End of the Sheath, the Protective Assembly being Adapted to Maintain a Desired Shape of the Distal End as Recited in Claim 3.

Claim 3 has been recited above. In the final rejection of claim 3, the Examiner states that an inside of a luer, i.e., the adapter 10, disposed at a first end of a sheath is adapted to maintain a desired shape of a distal end of the guide wire. *7/19/05 Office Action*, p. 7.

Appellants respectfully submit that neither the adapter 10 nor any other structure of the device in Samuels may be considered "a protective assembly" as recited in claim 3. As noted above, the adaptor 10 simply facilitates reinsertion of a guidewire into a previously opened packaging tube 40. Specifically, Samuels states that

[t]he joining configuration of the adapter ends and the

> packaging tube ends prevents a medical guidewire from getting stuck on the junctions between the packaging tube 40 and the adapter 10 during insertion.

Samuels, col. 3, lines 37 - 40. At no point does Samuels disclose or suggest that the adapter 10 protects any portion of the guidewire, and, in particular, a shaped distal end thereof. Essentially, the adapter 10 is a conduit which simply expands the ends 46 and 48 of the packaging tub 40 allowing the guidewire to be inserted thereinto. *Samuels*, col. 3, lines 5 - 12. It is unclear how an inside of the adapter 10 is a protective assembly which is adapted to maintain a desired shape of the distal end of the guidewire, as the Examiner has suggested. Samuels does, however, suggest that the adapter 10 may be enlarged to accommodate several guidewires. *Samuels*, col. 3, lines 50 - 55. However, enlarging the adapter only relates to increased-diameter guidewires and would not maintain the shapes thereof. Thus, it is respectfully submitted that Samuels neither discloses nor suggests "a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end," as recited in claim 3.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 3.

D. Samuels Does Not Disclose a Protective Assembly Adapted to Prevent Damage to a Curvature of the Distal End of the Elongated Medical Device as Recited in Claim 6.

Claim 6 has been recited above. In the final rejection of claim 6, the Examiner simply recites the subject matter of claim 6 verbatim. *7/19/05 Office Action*, p. 7. While the

Examiner has not cited any specific disclosure of Samuels which reads on the subject matter of claim 6, Appellants respectfully submit that Samuels does not disclose or suggest a protective assembly "adapted to prevent damage to a curvature of the distal end of the elongated medical device," as recited in claim 6.

In the final rejection, the Examiner has equated the adapter 10 of Samuels to the protective assembly of the present invention. *7/19/05 Office Action*, p. 7 (the final rejection of claim 3). In view of the above-description of the adapter 10 and the description in Samuels, it remains unclear how the adapter 10 prevents damage to a curvature of any portion of the guidewire, and, in particular, the distal end. In fact, the adapter 10 induces a curvature on the guidewire when it is being inserted into the packaging tube 40. Samuels states that a longitudinal axis of a duct 26 "forms an angle of less than 90 degrees with the longitudinal axis 15 of the conduit passage 14...." Samuels, col. 3, lines 29 - 34. The angle of the duct 26 relative to the tube 40 will induce a curvature on the guidewire as it is inserted into the tube regardless of a preformed curvature of the guidewire. By inducing a curvature on the guidewire, the preformed curvature of the guidewire may be damaged, if they are opposed. Thus, it is respectfully submitted that Samuels neither discloses nor suggests a protective assembly "adapted to prevent damage to a curvature of the distal end of the elongated medical device," as recited in claim 6.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 6.

III. The Rejection of Claims 8 and 15 - 20 Under 35 U.S.C. § 103(a) as Obvious over Samuels in View of Ullman Should Be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 8 and 15 - 20 were rejected under 35 U.S.C. 103(a) as obvious over Samuels in view of Ullman. *7/19/05 Office Action*, p. 9. The Examiner states that Samuels discloses the invention substantially as claimed except that the elongated medical device is a catheter, but that Ullman discloses a guidewire package for use with catheters. *Id.*

B. The References Do Not Disclose a Sheath Adapted to Contain a Catheter With a Shaped Distal Tip as Recited in Claim 8.

Claim 8 has been recited above and discussed with reference to Samuels and Ullman. Thus, it is respectfully submitted that neither Samuels nor Ullman, either alone or in combination, discloses a sheath "adapted to contain a catheter with a shaped distal tip," as recited in claim 8.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 8.

C. The References Do Not Disclose the Limitations Recited in Claim 15.

Claim 15 has been recited above and discussed with reference to Ullman. It is respectfully submitted that Samuels does not cure the above-described deficiencies of Ullman.

Specifically, neither Samuels nor Ullman, either alone or in combination, discloses or suggests "the hydration opening being positioned so that a desire proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15.

Samuels does not disclose or suggest that the adapter 10 or the tube 40 are suitable for hydration. The Examiner maintains that a port 30 on the adapter 10 is usable as a hydration opening, and that further evidence of this use is provided in the '006 patent (U.S. Patent No. 6,375,006 to Samuels). As noted above, the '006 never discloses or suggests that the nozzle 20 is "disposed between the first and second ends" of the pipe 12. In fact, this would be contrary to the disclosure of the '006 patent which repeatedly describes the apparatus as having one open end and one sealed end, teaching away from the present invention. Furthermore, Ullman does not teach that saline solution inserted into the chamber 13 via the filling port 30 is directed in any manner toward the two ends of the chamber 13. That is, as described above, fluid delivered to the isolation chamber 13 via the filling port 30 is never directed toward the entry port 21. Ullman does state that the fluid fills the isolation chamber 13 from the bottom-up, but never discloses or suggests that any fluid would be directed toward the entry port 21. Thus, it is respectfully submitted that neither Samuels nor Ullman, either alone or in combination, discloses or suggests "the hydration opening being positioned so that a desire proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 15 and claims 17, 18 and 20 which depend

therefrom.

D. The References Do Not Disclose a Protective Structure Disposed at the First End, the Protective Structure Maintaining a Desired Curvature of the Shaped Distal Tip as Recited in Claim 16.

Claim 16 has been recited above. In the final rejection, the Examiner states that Samuels discloses the invention substantially as claimed except for a protective structure, but that Ullman teaches the protective structure maintaining a desired curvature of the shaped distal tip of the elongated medical device. *7/19/05 Office Action*, pp. 9 - 10. Claim 16 has been discussed above with respect to Ullman. Therefore, it is respectfully submitted that Ullman does not disclose a protective structure maintaining a desired curvature of the shaped distal tip, as recited in claim 16. As such, Appellants respectfully submit that neither Samuels nor Ullman, either alone or in combination, discloses or suggests "a protective structure disposed at the first end, the protective structure maintaining a desired curvature of the shaped distal tip," as recited in claim 16.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 16.

E. The References Do Not Disclose the Catheter being a Microcatheter with a Shaped Distal Tip as Recited in Claim 19.

Claim 19, which depends from claim 15, recites "the catheter is a microcatheter with a shaped distal tip." In the final rejection, the Examiner states that Samuels discloses the

invention substantially as claimed except for a microcatheter with a shaped distal tip, but that Ullman teaches a catheter and Talonn teaches a catheter with a shaped distal tip. *7/19/05 Office Action*, p. 10. Initially, it should be noted that Talonn is specifically directed to a cardiac catheter package for encasing a cardiac catheter. *Talonn*, col. 1, lines 11 - 14. That is, Talonn never discloses that the catheter package is suitable for any other catheter types, including microcatheters. Furthermore, combination of the catheter of Talonn with the guide wire isolation chamber of Ullman has been discussed above. In particular, Talonn teaches a cap 18, sized to complement a housing portion 17, completely covering a catheter therein, which is contrary to the teaching of the tip 16a remaining exposed in Ullman. Ullman specifically states that the tip 16a remaining exposed serves a predefined purpose, i.e., allows the provider to grasp the guide wire 16 and pull it from the isolation chamber 13. Thus, it is respectfully submitted that neither Samuels, Ullman nor Talonn, either alone or in combination, discloses or suggests "the catheter is a microcatheter with a shaped distal tip," as recited in claim 19.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 19.

IV. The Rejection of Claims 1, 3, 6 - 9, 12, 13, 15 and 19 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 3,861,395 to Taniguchi Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 3, 6 - 9, 12, 13, 15 and 19 were rejected

under 35 U.S.C. 102(b) as being anticipated by Taniguchi. *7/19/05 Office Action*, p. 10. Taniguchi describes a catheter assembly 10 consisting of a body 12 and a protective bag 70 extending distally therefrom. *Taniguchi*, col. 3, lines 31 - 41. A distal end of the protective bag 70 is freely movable and does not attach to the body 12 in any manner.

B. Taniguchi Does Not Disclose a Hydration Opening Disposed Between the First and Second Ends of the Sheath as Recited in Claim 1.

Claim 1 has been recited above. In the final rejection, the Examiner states that Taniguchi discloses a protective sheath and a hydration opening, i.e., an unnumbered portion beneath a reservoir 31. *7/19/05 Office Action*, pp. 10 - 11.

The Examiner states that Taniguchi shows a reservoir 31 disposed between a proximal end of the body 12 and a distal end of the bag 70. Initially, it should be noted that Taniguchi does not provide any disclosure with regard to reference numeral 31 and does not include any mention of "a reservoir." Thus, it is unclear what feature numeral 31 is drawn to and what function is performed by this element. Taniguchi does provide, however, that a lubricant bladder 32 is punctured by a spike 33 when a cover 30 enclosing the bladder 32 is depressed. The bladder 32 empties onto a proximal end of a catheter 68. It is respectfully submitted that a one-time covering of the proximal end of the catheter 68 in lubricant cannot be equated to the "hydration opening," as recited in claim 1. Thus, it is respectfully submitted that Taniguchi does not disclose or suggest "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

The Examiner suggests that the body 12 combined with the bag 70 makes up a structure equateable with the recited "protective sheath." Applicants respectfully submit that the body 12 and the bag 70 are separate structures, neither of which can be considered a protective sheath, as recited in claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 1 and claims 7, 9, 12 and 13 which depend therefrom.

C. Taniguchi Does Not Disclose a Protective Assembly Disposed at the First End of the Sheath, the Protective Assembly being Adapted to Maintain a Desired Shape of the Distal End as Recited in Claim 3.

Claim 3 has been recited above. In the final rejection, the Examiner repeats the subject matter of claim 3 and states that an unidentified part of the catheter assembly 10 in Taniguchi functions as the claimed "protective assembly." *7/19/05 Office Action*, p. 11. Appellants respectfully submit that Taniguchi neither discloses nor suggests "a protective assembly" as recited in claim 3.

The Examiner has not identified or described any part of Taniguchi which, first, is equateable to the claimed protective assembly, and, second, maintains a desired shape of a distal end of elongate medical device. The bag 70 is not described as having any material or structural attributes which would maintain a desired shape of the catheter 68. Furthermore, as shown in Fig. 1 of Taniguchi, the distal end 66 of the catheter 68 is exposed from catheter assembly 10.

Thus, there is no enclosure or other structure which maintains the shape of either end of the catheter 68. Thus, it is respectfully submitted that Taniguchi neither discloses nor suggests a " protective assembly being adapted to maintain a desired shape of the distal end," as recited in claim 3.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 3.

D. Taniguchi Does Not Disclose a Protective Assembly Adapted to Prevent Damage to a Curvature of the Distal End of the Elongated Medical Device as Recited in Claim 6.

Claim 6 has been recited above. In the final rejection, the Examiner simply repeats the subject matter of claim 6 verbatim. *7/19/05 Office Action*, p. 11.

Similar to the above-reasoning with reference to claim 3, the Examiner has not identified or described any part of Taniguchi which is adapted to prevent damage to a curvature of the distal end of the elongate medical device. First, the catheter 68 is not disclosed as exhibiting a curvature at a distal end thereof. That is, Fig. 1 of Taniguchi shows substantially straight ends of the catheter 68. In any case, the bag 70 is not described as having any material or structural attributes which would prevent damage to a curvature of the distal end of the catheter 68. Thus, it is respectfully submitted that Taniguchi neither discloses nor suggests a " protective assembly being adapted to maintain a desired shape of the distal end," as recited in claim 6.

Thus, Appellants respectfully request that the Board overturn the Examiner's

rejection under 35 U.S.C. § 102(b) of claim 6.

E. Taniguchi Does Not Disclose a Sheath Adapted to Contain a Catheter with a Shape Distal Tip as Recited in Claim 8.

Claim 8 has been recited above. Although the final rejection stated that claims 6 - 9 were rejected in view of Taniguchi, the Examiner failed to address the rejection of claim 8. In any case, it is respectfully submitted that Taniguchi neither discloses nor suggests that "the sheath is adapted to contain a catheter with a shaped distal tip," as recited in claim 8. Again, the bag 70 does not have a defined structure which would suggest that it contains a catheter with a shaped distal tip. Also, each of the figures in Taniguchi show the catheter 68 with substantially straight ends. Thus, it is respectfully submitted that Taniguchi neither discloses nor suggests that "the sheath is adapted to contain a catheter with a shaped distal tip," as recited in claim 8.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 8.

F. Taniguchi Does Not Disclose the Subject Matter Recited in Claim 15.

Claim 15 has been recited above. In the final rejection, the Examiner rejected claim 15 for the same reasons as given with respect to claim 1. *7/19/05 Office Action*, pp. 10 - 11.

The bag 70 in Taniguchi does not include a hydration opening between proximal and distal ends thereof. And, the body 12 does not include "a first end...adapted to receive a

distal end of the elongated medical device and a second end...adapted to receive a proximal end of elongated medical device." Thus, it is respectfully submitted that Taniguchi does not disclose or suggest "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof," as recited in claim 15.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 15.

G. Taniguchi Does Not Disclose a Protective Structure Disposed at the First End, the Protective Structure Maintaining a Desired Curvature of the Shaped Distal Tip as Recited in Claim 16.

Claim 16 has been recited above. In the final rejection, claim 16 was rejected for the same reasons as stated above with respect to claim 6. *7/19/05 Office Action*, pp. 11. That is, the Examiner did not identify any part or disclosure of Taniguchi which is adapted to prevent damage to a curvature of the distal end of the elongate medical device. Thus, it is respectfully submitted that Taniguchi neither discloses nor suggests a " protective structure disposed at the first end, the protective structure maintaining a desired shape of the shaped distal tip," as recited in claim 16.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 16.

H. Taniguchi Does Not Disclose the Catheter being a Microcatheter with a Shaped Distal Tip as Recited in Claim 19.

Claim 19 has been recited above. In the final rejection, claim 19 was rejected for the same reasons as stated above with respect to claims 1 and 15. *7/19/05 Office Action*, pp. 10 - 11.

Initially, it should be noted that Taniguchi generally describes a catheter for use with the catheter assembly 10 and never discloses that a microcatheter is suitable for use therewith. Thus, it is respectfully submitted that Taniguchi neither discloses nor suggests that "the catheter is a microcatheter with a shaped distal tip," as recited in claim 19.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 19.

V. The Rejection of Claim 4 Under 35 U.S.C. § 103(a) as Obvious Over Taniguchi in View of U.S. Patent No. 4,805,611 to Hodgkins Should Be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claim 4 was rejected under 35 U.S.C. 103(a) as obvious over Taniguchi in view of Hodgkins. *7/19/05 Office Action*, p. 12. The Examiner stated that Taniguchi discloses the invention substantially as claimed except for a luer or adapter capable of receiving a syringe, but that Hodgkins discloses an adapter 67 for receiving the syringe. *Id.*

B. The References Do Not Disclose the Subject Matter of Claim 4.

Claim 1 has been recited above. Hodgkins discloses an aspirating device consisting of a flexible catheter which is adapted for insertion into the trachea. *Hodgkins*, Abstract. A flexible envelope is connected to the device so that substantially all portions of the catheter between a catheter connector fitting and a proximal opening of the device are within the envelope. *Id.* As such, it is respectfully submitted that Hodgkins does not cure the above-described deficiencies of Taniguchi. Thus, because claim 4 depends from, and, therefore includes all of the elements recited in claim 1, it is respectfully submitted that neither Hodgkins nor Taniguchi, either alone or in combination, discloses or suggests the subject matter of claim 4.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 4.

VI. The Rejection of Claims 1, 4, 7, 9, 10 and 11 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 4,805,611 to Laak Should Be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 1, 4, 7, 9, 10 and 11 were rejected under 35 U.S.C. 102(b) as anticipated by Laak. *7/19/05 Office Action*, p. 13. The Examiner stated that Laak discloses a protective sheath and a hydration opening as recited in claim 1. *Id.*

Laak describes a leaching field consisting of a manifold for receiving effluent from a septic tank and directing the effluent through parallel outlets in the manifold. In support of the rejection, the Examiner states that the leaching field in Laak could hold an elongate

medical device, and as such, anticipates claim 1 of the present invention. At no point does Laak disclose or suggest that the manifold includes "a protective sheath including a lumen sized to receive a body of *the elongated medical device*," as recited in claim 1. In fact, the manifold receives a continuous flow of effluent therethrough from a septic tank. As such, Laak never suggests that an elongated medical device is received in the manifold and subjected to contact with the flow of effluent. Furthermore, it is respectfully submitted that one of skill in the art would have been initiated to employ the teaching of Laak as described by the Examiner in view of the goals of sterility and prevention of infection/contamination, which are common in the medical field in addition to the numerous other differences in size, materials, etc. which separate these fields. Thus, it is respectfully submitted that Laak neither discloses nor suggests the subject matter of claim 1.

Thus, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 102(b) of claim 1 and claims 4, 7 and 9 - 11 which depend therefrom.

8. Conclusions

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) and indicate that claims 1 - 20 are allowable.

Respectfully submitted,

Date: November 21, 2005

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CLAIMS APPENDIX

1. A protective package for an elongated medical device, comprising:

a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device; and

a hydration opening disposed between the first and second ends of the sheath.

2. The protective package according to claim 1, wherein the sheath is formed as a hoop and wherein the medical device is a catheter.

3. The protective package according to claim 1, further comprising a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

4. The protective package according to claim 1, further comprising a luer attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

5. The protective package according to claim 1, further comprising an adapter coupled to the hydration opening for receiving a syringe.

6. The protective package according to claim 3, wherein the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device.

7. The protective package according to claim 1, wherein the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

8. The protective package according to claim 6, wherein the sheath is adapted to contain a catheter with a shaped distal tip.

9. The protective package according to claim 1, wherein the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

10. The protective package according to claim 9, wherein the desired ratio is one to one.

11. The protective package according to claim 1, wherein the hydration opening is substantially equidistant from the first and second ends.

12. The protective package according to claim 1, wherein the hydration opening is oriented to direct an amount of flow toward the first end which is different than an amount of flow directed toward the second end.

13. The protective package according to claim 12, wherein the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

14. The protective package according to claim 13, wherein the desired ratio is one to one.

15. A catheter kit comprising:

a catheter having a shaped distal tip;

a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter;

a first end of the tubular enclosure being adapted to receive the shaped distal tip;

a second end of the tubular enclosure being adapted to receive a proximal end of the catheter; and

a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends.

16. The catheter kit according to claim 15, further comprising a protective structure disposed at the first end, the protective structure maintaining a desired curvature of the shaped distal tip.

17. The catheter kit according to claim 15, wherein the tubular enclosure is coiled to form a hoop.

18. The catheter kit according to claim 15, wherein a hydrating fluid introduced into the tubular enclosure via the hydration opening is divided such that the proximal end and the distal end of the catheter are substantially equally hydrated.

19. The catheter kit according to claim 15, wherein the catheter is a micro-catheter with a shaped distal tip.

20. The catheter kit according to claim 15, wherein the hydration opening is substantially equidistant between the first and second ends.

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.